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ATTACHMENT 11

510(K) SUMMARY K992660

URF Digital - OT

Submitted by:
Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

August 6, 1999

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **Contact Person**

Ms. Malgorzata Stanek
Phone: (732) 321-3950 Fax: (732) 321-4841

2. **Device Name and Classification**

Trade Name:	URF Digital - OT
Classification Name:	Image Intensified Fluoroscopic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1650
Device Class:	Class II
Device Code:	90JAA

3. **Intended Use**

The URF Digital - OT is a device intended to visualize anatomical structures by converting a pattern of X-ray into a visible image through electronic amplification. The system has medical applications ranging from gastrointestinal examinations to cranial, skeletal, thoracic and lung exposures as well as examination of the urogenital tract. The units may also be used in lymphography, endoscopy, myelography, venography, pediatrics, arthrography, interventional radiology, digital angiography, and digital subtraction angiography (DSA).

4. **Substantial Equivalence**

The URF Digital - OT is substantially equivalent to Siemens Siregraph T.O.P. 33 and 40 that are currently in commercial distribution. The Siregraph T.O.P. 33 and 40 were described in premarket notification K970734, which received FDA clearance on April 21, 1997.

5. Device Description

URF Digital - OT is a universal fluoroscopic X-ray diagnostic system intended for use in Digital Fluoro Radiography (DFR) with an undertable image intensifier. The system is operated either via tableside control or via remote control console.

The URF Digital - OT is available in two versions, the URF Digital - OT TOP and the URF Digital - OT Comfort.

6. Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device

The URF Digital - OT has the same technological characteristics as the predicate Siregraph T.O.P 33 and 40. Like the Siregraph T.O.P 33 and 40, the URF Digital - OT consists of the basic system (patient support table) and standard system components (i.e. X-ray generator, X-ray tube, image intensifier, TV system, digital imaging system, monitors, optional Bucky wall stand and optional ceiling-mounted support for a second X-ray tube).

The Siregraph TOP and the URF Digital - OT differ such that, in the URF Digital - OT:

- The basic system and system stand are created from modular components for higher flexibility.
- A new digital imaging system with CCD camera has been added.
- The unit is configured with the latest commercially available system components.

Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 1999

Ms. Malgorzata Stanek
Senior Technical Specialist
Siemens Medical Systems, Inc.
186 Wood Ave. South
Iselin, NJ 08830

Re: K992660
URF Digital-OT Image-Intensified Fluroscopic X-ray System
Dated: August 6, 1999
Received: August 9, 1999
Regulatory class: II
21 CFR 892.1650/Procode: 90 JAA

Dear Ms. Stanek:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 1

INDICATIONS FOR USE

510(k) Number (if known): K992660

Device Name: URF Digital - OT

Indications for Use:

The Siemens URF Digital - OT is intended to visualize anatomical structures by converting a pattern of X-ray into a visible image through electronic amplification. The system has medical applications ranging from gastrointestinal examinations to cranial, skeletal, thoracic and lung exposures, as well as examination of the urogenital tract. The URF Digital - OT may also be used in lymphography, endoscopy, myelography, venography, pediatrics, arthrography, interventional radiology, digital angiography, and digital subtraction angiography (DSA).

Concurrence of the CDRH, Office of Device Evaluation (ODE)

David A. Clegorn

(Division Sign-Off)
Division of Reproductive, Abdominal, **ENT,**
and Radiological Devices
510(k) Number K992660

Prescription Use X OR Over-The-Counter Use _____
(per 21 CFR 801.109)